

1.0 Planning the Assessment

1.1 Introduction

In order to effectively design and implement an ERA that is scientifically defensible and will support a risk management decision regarding site cleanup and disposition, the RPM must begin managing the ERA early within the overall cleanup process. This ERA management includes a number of important considerations, such as identification of the appropriate scope for the ERA, identification of staffing requirements, development of a statement of work, review of ERA work proposals, and coordination of the ERA process and activities with regulators and Trustees. This portion of the web site presents guidance to aid the RPM in scoping and managing the ERA within the Navy tiered approach for ERA. Additional guidance regarding tier-specific project planning is presented in [Section 2](#) (Tier 1), [Section 3](#) (Tier 2) and [Section 4](#) (Tier 3) of the *Ecorisk Process* portion of this website.

1.2 Early Project Planning

Early project scoping assists the RPM in ensuring that their site undergoes an evaluation of ecological risk that can support a risk management decision. Such project planning helps determine the work scope and the level of resources necessary for the ERA, initiates interaction and coordination among all members of the cleanup team (e.g., Navy, contractors, regulators and stakeholders) thereby encouraging valuable dialogue and enhancing overall project understanding, and aids in the development of an overall project strategy from assessment to cleanup.

1.2.1 Objectives of the ERA

A key issue that must be identified as early in the process as possible is the objective of the ERA. You do not want to initiate a detailed and potentially costly ERA simply because the law and Navy Policy states that you must evaluate ecological risks. An unfocussed approach will more often than not result in an evaluation that is not directed at the true issues at the site, but instead expends time and funding gathering data that may or may not help to support a risk management decision for the site.

Although the overall objectives of the ERA are to identify whether a site poses acceptable and unacceptable ecological risks and to support a risk management decision regarding site cleanup, each Tier of the Navy ERA process (Figure 1.1) will have somewhat different objectives. For example, the objectives for a Tier 1 SRA include:

- Identification of sites and contaminants that do not pose unacceptable risks and thus may be eliminated from further consideration in the ERA process,
- Identification of sites and contaminants that warrant immediate action, and

- Identification of sites and contaminants requiring further ERA and that must therefore continue within the ERA process.

In contrast, Tier 2 objectives will be focused on identifying unacceptable risks, developing preliminary remediation goals (PRGs) if appropriate, and supporting a decision of whether remediation will be necessary. In contrast, the objectives for Tier 3 focus on the evaluation of remedial alternatives relative to risk reduction and environmental impacts in order to select a remedy that effectively balances human health and ecological risks while minimizing environmental impacts to the fullest extent possible.

Make sure the overall and the tier-specific ERA objectives are clearly defined and understood by the entire project team. Similarly, these objectives should be identified to the regulators and stakeholders for their review and concurrence. Keep in mind that such early discussions may result in changes being made to the initially identified ERA objectives. If alternative objectives are proposed, the RPM should not agree to their incorporation without first ensuring that the alternative objectives are fully understood by the RPM and their risk assessment team. This understanding should include not only an understanding of the objectives from an ecological perspective, but also from a perspective of cost, effort, and other resource requirements. In other words, do the objectives make sense from a cleanup perspective, and how may these alternative objectives affect overall cleanup effort and cost, schedules, and FFA milestones.

Concurrence among all parties regarding the ERA objectives should be documented. Additional guidance regarding tier-specific ERA objectives is provided elsewhere on this web site. Early coordination with regulators and stakeholders is discussed later in this portion of the guidance (see Section 1.3.2).

1.2.2 Technical Requirements for the ERA

The technical requirements for conducting an ERA must be considered early in the ERA planning process. Early identification and consideration of these requirements will aid in scoping the effort and cost estimates, and in the development of appropriate sampling and analysis plans. Technical requirements (which will be site-specific) may include sampling methods, laboratory analyses, and data evaluation methods, and these must be related to the media and ecological resources to be evaluated. These early technical requirements are then refined as the site proceeds through the ERA process. The specific technical requirements for the ERA will be a function of which tier the Navy ERA process (Figure 1.1) the site is entering. In general, Tier 1 will have the least complex technical requirements, while Tier 2 will have the most diverse technical requirements. Additional tier-specific information and guidance regarding specific technical requirements are presented in [Section 2](#) (Tier 1), [Section 3](#) (Tier 2) and [Section 4](#) (Tier 3) of the [Ecorisk Process](#) portion of this guidance website.

1.3 Staffing and Coordination

Successfully planning and managing the ERA will be strongly dependant on a number of team-related issues, including (1) the risk assessment expertise available to you, (2) early and frequent coordination among the various tasks (site characterization, risk assessment, remedial technology identification) and their associated technical disciplines, and (3) early and frequent coordination among the risk assessment team (Navy, contractors, regulators) and with the Trustees.

1.3.1 Identifying the Appropriate Risk Assessment Expertise

Because of the diverse nature of ecosystems, it is unlikely that any one ecological risk assessor (or any ecologist for that fact) would be an expert in all aspects of ecology and ERAs. Rather, ecologists and ecological risk assessors tend to have expertise in one area (e.g., wildlife management, fish ecology, waterfowl, desert invertebrates, community ecology, and behavior) and a general knowledge in other areas of ecology. In contrast, it is unlikely that the ERA will be addressing only one component of the ecosystem. Thus, it is important that the risk assessor(s) supporting you in the ERA of your site possess the appropriate expertise. Furthermore, it is important (especially in Tier 2) that the ERA team also includes statistical expertise to ensure for the design of scientifically defensible investigations.

The nature of the ecological resources at the site which are likely to be of greatest concern should be considered when selecting ecological risk assessor support. For example, if a site supports a sea otter population, expertise in marine mammals would be appropriate. Alternately, if the site supports a shorebird nesting colony, expertise in shorebird ecology would be appropriate. If the potentially affected area were known fish nursery habitat, expertise in fish ecology would be appropriate.

The RPM should contact the appropriate in-house ERA point-of-contact (if available) and/or the NFESC ERTAT for assistance in determining the likely ERA areas of expertise needed for the assessment, and this expertise should be clearly identified in the Statement of Work (SOW) developed by the RPM. In addition to the specific technical expertise of the risk assessor, one should also request and evaluate the assessor's credentials with regard to the degree of prior experience with similar ERA problems or issues.

1.3.2 Coordinating Site Characterization and Risk Assessment Staff and Activities

As the RPM, you will be managing a number of RI activities, including those related to site characterization, HHRA, and ERA. These activities, which may or may not be occurring concurrently, are typically conducted by different support contractors and staff. Because conduct of the ERA (and the HHRA) and any subsequent risk management decisions are strongly dependent on contaminant data, and remdial decisions must

balance human health and ecological risks, it is critical that you bring the ERA and site characterization staff together as early as possible. By coordinating the Tier 1 and Tier 2 ERA activities and data needs of all staff, you lessen the chance that additional sampling (with associated additional costs and time requirements) will be required for the site.

During these early coordination meetings, the risk assessors should identify the areas (e.g., habitats) and media (e.g., offshore sediments) that they consider likely to be evaluated by the ERA. The risk assessors should also identify the analytical detection limits necessary for the environmental data to be usable in the ERA. Too often, environmental data are collected with only the HHRA in mind, and HHRA analytical detection limits are often greater than known ecological effects levels. This makes the data unusable in the ERA and forces another round of field sampling and laboratory analyses.

By identifying the ERA and HHRA data requirements early in the RI process, they can be integrated into the site characterization sampling design, thereby reducing mobilization costs and data collection. In the absence of this type of coordination and communication, there is the strong potential that the environmental data collected during site characterization will be inadequate to support both ERA and HHRA evaluations, thereby requiring a resampling and analysis (with lower detection limits) for the same constituents.

In a similar manner, the Tier 3 ERA evaluations should be coordinated with the other FS components. The ecological risk assessor (and also the human health risk assessor) will use the results of the Tier 2 ERA to develop preliminary remediation goals. These risk-based media concentrations, together with site physical characterization data such as geology, topography, and hydrology, will then be used to develop remedial alternatives for further evaluation in the FS and Tier 3. The remedial design staff, in turn, will provide the ecological risk assessor with alternative information related to implementation and operation (e.g., excavation footprint, residual contamination, construction requirements and activities, mitigation, etc.). It is this information, together with the residual contamination that the ecological risk assessor will be evaluating in the Tier 3 ERA.

1.3.3 Coordinating with Regulators

Upon completion of the ERA, the ERA and the resultant risk management decision are provided to the regulators (typically the EPA and the State) for their review and concurrence. If the ERA was well scoped, designed and conducted, the resultant evaluation will provide a scientifically based, defensible risk assessment that will support risk management decisions. In addition, a well-scoped and designed ERA should also help facilitate regulator concurrence of the risk assessment results as well as the subsequent risk management decisions. Difficulties in securing such concurrence may be due, in part, to regulator disagreements on ERA goals, objectives, and/or methods.

To minimize potential problems related to regulator concurrence, it is critical that the regulators and other appropriate stakeholders be brought as early in the process as possible into the ERA process. This early involvement serves to identify regulator issues and concerns before the goals, objectives, and methods of the ERA are finalized and implemented, and help in resolving regulator issues and concerns before the ERA is initiated. The CNO Policy for conducting ERAs identifies extensive communication among and concurrence (if obtainable) from the regulators prior to proceeding from one step to the next of the ERA process. This early coordination is especially important for the Tier 2 BERA, which often involves the greatest commitment of cost and effort of the three ERA tiers. The Tier 2 BERA also includes the greatest number of factors over which there may be disagreements (such as the selection of endpoints, study designs, methods for risk characterization, and data analysis). Additional information regarding regulator involvement can be found in Section 2.2.3 and Section 3.1.3 of this web site.

1.3.4 Involving Natural Resource Trustees

The CNO Policy for conducting ERAs encourages Trustee involvement in the cleanup process and in the ERA process in particular. As with the early involvement of regulators, early involvement of Trustees will identify their natural resource concerns at a point in the ERA process where some issues and concerns may be readily addressed by appropriate ERA study design. Furthermore, early identification and consideration of Trustee concerns may aid in the development of remedial alternatives (that are evaluated in Tier 3) that address the Trustee concerns to the extent practicable, and minimize potential natural resource injuries during cleanup. The DoD Deputy Undersecretary for Environmental Security recently (2 May 2000) issued interim policy for integrating natural resource activities into all types of cleanup, including those conducted under CERCLA, RCRA, and DERP. This policy identifies early coordination with Trustees early in the site assessment, investigation, and remedy selection process.

While early Trustee involvement is strongly encouraged, it is also very important to keep in mind that it is the Navy and the regulators that make all final risk management decisions for your site, and not the Trustees. Do solicit and listen to input from the Trustees, but keep in mind that the other Trustees do not have a decision-making role at sites where the Navy is the potentially responsible party (PRP), and that Trustee issues should not drive the scope and objectives of the ERA.

1.4 Preparing the ERA Statement of Work

1.4.1 Purpose of the Statement of Work

The ERA Statement of Work (SOW) is critical for the RPM for implementing the ERA and tracking its progress. In the SOW the RPM spells out the specific tasks to be conducted in the ERA, and the schedule and deliverables for each task. In other words,

the SOW represents your requirements and expectations for the ERA, and the risk assessors orders and requirements for conducting the ERA.

The EPA has identified a number of benefits associated with a clear, specific and thorough SOW (EPA 1992; may be viewed or downloaded at: <http://www.epa.gov/superfund/programs/risk/tooleco.htm#GG>). These benefits include:

- **Preventing too much work.** Without appropriate direction, the ERA may include more work than is necessary to characterize risks,
- **Preventing too little work.** Without appropriate direction, the ERA may not adequately evaluate ecological risks due to insufficient data and inappropriate statistical analyses,
- **Preventing incorrect work.** If the SOW is not specific enough, studies may be designed and conducted which, although technically/academically interesting, are completely inappropriate for supporting a risk management decision, and
- **Preventing inadequate quality assurance/quality control.** If the SOW does not identify the need for the development of data quality objectives, the ERA may not generate data of a quality level sufficient to support a risk management decision.

1.4.2 Preparing a Statement of Work: Format and Content

Regardless of the scope of the SOW, each should include:

- A description of the general scope of the ERA work to be conducted,
- A requirement for the ERA to follow the CNO Policy;
- A brief discussion of the project background;
- A description of the specific tasks to be conducted;
- Specification of required ERA deliverables;
- A description of the expertise and experience required for the ERA; and
- A description of other expectations and requirements, such as meeting attendance and monthly progress reports.
- Identification of the specific guidance (such as the EPA Superfund Guidance for ERA, EPA Regional Guidance that is consistent with the Superfund Guidance, etc.) with which the contractor must comply.

The general scope should provide sufficient information for the contractor to understand the need, goals, and objectives of the ERA. The background description should provide enough information (either directly or in the form of readily available reference materials) to permit the contractor to formulate an approach for conducting the ERA. The description of tasks should be as clear, concise, and detailed as possible. For each identified task, a description of the expected activities should be included together with identification of any deliverables associated with the task. Expected deliverables may include draft and final reports, meeting minutes, and progress reports.

To avoid any confusion regarding expected deliverables (types and dates), a separate schedule of all deliverables for all tasks should be included with the SOW. The SOW

should also identify the requirement for internal Navy review of all contractor prepared materials, and this review requirement should be clearly identified in the overall project schedule. The SOW should also identify the specific technical expertise needed for the ERA, as indicated during early project planning.

Internal Navy Review Drafts

An internal draft of all products (in either electronic or hard copy format) should be provided to the RPM prior to the release by the Navy of any project materials to the regulators or other appropriate parties. This requirement, which should be clearly specified in the SOW, insures that the RPM and the project team are fully aware of all assumptions, methods, data sources, and other pertinent information that will be employed in the proposed ERA, prior to project review by the regulators. Internal review drafts also allow the RPM to identify project specifics where additional technical and/or procedural clarification or rationale may be warranted, and where Trustee or public sensitivities may be important. The internal review draft serves as the vehicle for discussions within the Navy team regarding the work scope, assumptions, methods, etc., leading to a unified Navy consensus prior to formal interactions with the regulators.

In specifying deliverables, it is important to clearly identify and incorporate Scientific Management Decision Points (SMDPs) as required deliverables. SMDPs represent agreement points between the Navy and the regulators regarding a variety of important ERA components, including problem formulation, assessment and measurement endpoints, work and sampling plans, and final reports. By identifying these SMDPs as required deliverables, it precludes the ERA from proceeding to the next phase of the ERA without first securing approval from the RPM and concurrence from the regulators (as can be obtained).

For example, Tier 2 of the CNO Policy for conducting ERAs (Figure 1.1) includes the preparation of a Work Plan (WP) and a Sampling and Analysis Plan (SAP). The ERA should not proceed to the next step until there is concurrence on these plans among all appropriate parties (e.g., Navy and the regulators). This concurrence is accomplished through the early involvement and interaction with the regulators, and is documented in the draft WP and SAP. The draft WP and SAP represent the SMDP for Step 4 of the Tier 2 BERA. Note that the internal review copies of both draft and final plans should be submitted by the contractor to the RPM for Navy review, prior to submittal by the Navy to the regulators. If regulator concurrence is not obtained, you should document the issues in question and the opposing views and positions on those issues and elevate the matter to upper management (and appropriate legal counsel) before moving to the next step in the Tier.

The SOW should identify both the draft and final versions of the WP and SAP (along with internal review copies of each) as required deliverables, and the contractor should not proceed to the next step of Tier 2 without the approval of the RPM following the

signing of the final WP and SAP. In the absence of regulatory concurrence, the tasks identified in the draft WP and SAP should not be implemented without direct instruction from the RPM. The SOW should also identify any issues, activities, or other considerations that will be required. These may include, but are not limited to:

- Navy, Federal, or other guidance or regulations with which the ERA must comply;
- Navy POCs regarding work directions, budget, contracting issues, etc.;
- Requirements for dealing with the public;
- Requirements on the distribution of project reports and data;
- Format of project submittals (electronic, CD ROM, paper copy, etc.); and
- Procedures for revising the scope of work.

The scope of the SOW will be dependent on where your site is in the ERA process. For a Tier 1 ERA, the SOW may be relatively straightforward and simple, while the increased complexity of a Tier 2 ERA will require a much more detailed SOW. The SOW for a Tier 3 ecological evaluation would focus on the nine CERCLA criteria for evaluating remedial alternatives (see [Section 4](#)).

1.4.3 Reviewing ERA Work Proposals

In response to a Navy SOW, a contractor will prepare and submit an ERA work proposal which describes how the tasks and other requirements identified in the SOW will be accomplished. It is important that you carefully review and understand the contractor proposal. In this review, pay close attention to how much the work proposal deviates from the expectations and requirements identified in the SOW, and ask for explicit assumptions (e.g., it is assumed that site access will be provided as needed; it is assumed that samples will be analyzed according to the QAP protocol with appropriate qualifiers). It is important that you understand why the expectations and requirements of the SOW have been changed, and if necessary request additional information and rationale for any such deviations. Do not accept the proposal until you are satisfied with the changes.

1.5 Work Plan

Prior to proceeding with site-specific data collection or analysis, the support contractor must develop a WP that clearly describes the nature of the work to be conducted and how that work will be used to support a risk management decision for the site. The information presented in the WP will depend on the specific Tier under which the ERA is to be conducted.

For the Tier 1 SRA, the WP should include:

- A general overview of the site, including its physical and ecological setting,
- A summary of the known or suspected release,
- A summary of past investigations and existing data,
- A description of the approaches to be used to evaluate pathways, model doses, and characterize risks, and

- The values to be used for the screening risk characterization.

For the Tier 2 BERA the WP should:

- Summarize the Tier 1 SRA results and risk management decision,
- Identify the COPCs retained by the Tier 1 SRA and to be evaluated in the BERA,
- Identify the assessment and measurement endpoints to be addressed in the BERA,
- Identify the exposure pathways linking the COPCs and the assessment endpoints,
- Present the risk questions and hypotheses to be addressed by the BERA, and
- Provide the conceptual site model for the site.

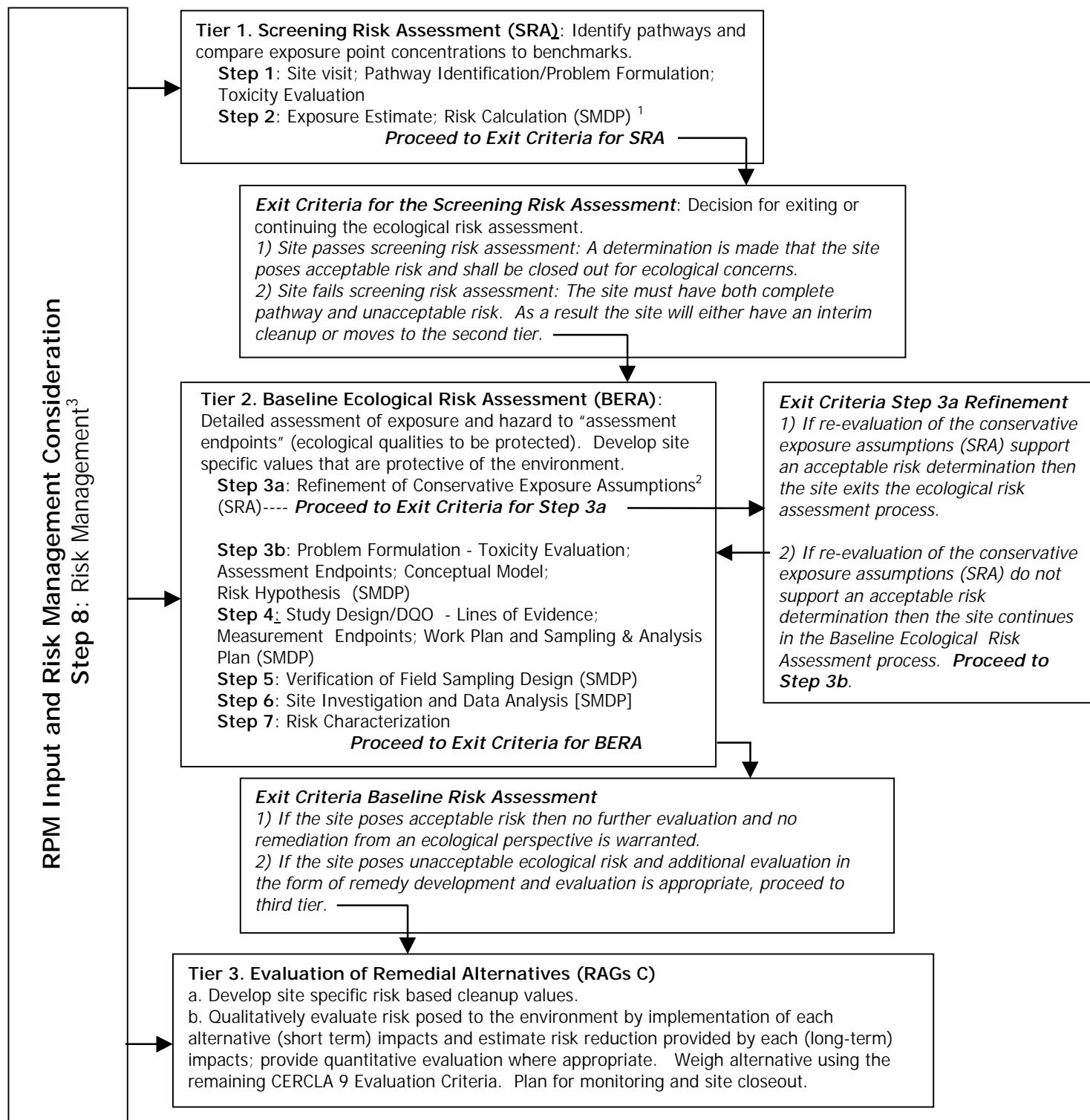
For the Tier 3 Evaluation of Alternatives, the WP should:

- Summarize the results of the Tier 2 ERA and the subsequent risk management decision,
- Identify the COCs and the associated PRGs.
- Identify the criteria to be used for evaluating the remedial alternatives, and
- Describe how ecological resources will be considered by each criterion.

Additional information on tier-specific WPs can be found in [Section 2](#) (Tier 1), [Section 3](#) (Tier 2), and [Section 4](#) (Tier 3) of the [Ecorisk Process](#) portion of this website.

1.6 Assistance in Preparing SOWs and Reviewing ERA Work Proposals and Work Plans

A generic SOW for use by RPMs in developing site-specific SOWs may be viewed or downloaded by [clicking here](#). This generic SOW addresses ERA activities associated with the Tier 1 SRA and the Tier 2 BERA, and can be readily modified for Tier 3. For additional assistance with preparing SOWs, and for reviewing ERA work proposals and WPs, contact the NAVFAC ERTAT (<http://erb.nfesc.navy.mil>) then select in order: *Navy Support*, *Technology Application Teams*, and *Ecological Risk Assessment*). In addition, the EPA Office of Solid Waste and Emergency Management has published an ECO Update Bulletin (ECO Update, Vol. 1, No. 4, 1992) that addresses the development of an ERA work scope. This bulletin provides helpful information for developing a SOW, and may be accessed at <http://www.epa.gov/superfund/programs/risk/tooleco.htm>.

Figure 1.1. Navy Ecological Risk Assessment Tiered Approach

Notes: 1) See EPA's 8 Step ERA Process for requirements for each Scientific Management Decision Point (SMDP).
 2) Refinement includes but is not limited to background, bioavailability, detection frequency, etc.
 3) Risk Management is incorporated throughout the tiered approach.